

make and/or use the invention. Applicants respectfully traverse the rejection.

The Examiner has admitted, "The prior art of the present application indicates several different species of bacteria can accumulate gold, silver, and other minerals from sea water, and a psychrophilic crenarchaeon inhabits a marine sponge ..." While the Examiner admits that Applicants' specification discloses a psychrophilic crenarchaeon inhabits a marine sponge, he then argues that the specification does not provide adequate evidence of how bacteria "could be delivered to the flora of sponges and populate sponges such that the bacteria could grow to reach appreciable numbers so as to be able to concentrate metals and minerals."

The essence of this basis for the rejection ignores the position taken by the courts that the applicant is not required to reduce the invention to practice but simply to teach how to make and use the invention. Applicants respectfully assert that the specification does in fact teach how to make and use the invention as claimed.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the application coupled with information known in the art without undue experimentation. United States v. Teletronics, Inc., 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). "Whether making and using an invention would have required undue experimentation, and thus whether a disclosure is enabling under 35 U.S.C. §112, first paragraph (1994), is a legal conclusion based upon underlying factual inquiries." In re Cortright, 49 USPQ2d 1464, 1465 (Fed. Cir. 1999). Factors to consider include the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill

in the art, the level of predictability in the art, the amount of experimentation needed to make or use the invention based on the content of the disclosure. *See In re Wands* at 404.

Importantly, the PTO cannot make an enablement rejection “unless it has reason to doubt the objective truth of the statements contained in the written description.” *See In re Cortright* at 1466. The Examiner has not provided a reference to any citation that would indicate that Applicant’s statements are untrue or lack a reasonable basis for belief. As discussed below, the Applicants have, in the specification, fully supported the prophetic example and the basis for their invention. Further, the Examiner’s continued insistence that this evidence must show that the bacteria can grow to “appreciable numbers” would require an actual reduction to practice, which is totally beyond the requirements of 35 U.S.C. §112, first paragraph, and is inconsequential to the inventors right to claim the invention as conceived.

Applicants respectfully submit that the specification provides adequate support for the claims as written. The claimed invention is a method of recovering metals and minerals from sea water, comprising: contacting a sponge which harbors a bacteria capable of concentrating said metal or mineral with said sea water to concentrate the metal or mineral in the bacteria and recovering the concentrated metal or minerals from the bacteria (Claims 23-26). The specification discloses that sponges (1) can be cultivated and grown, (2) can harbor a microorganism including bacteria capable of concentrating metals or minerals from aqueous media, (3) are able to process relatively large volumes of water per unit mass, and (4) draw in particulate matter with water. *See* Page 3, lines 7-25, Page 4, line 18 to Page 5, line 2, and Page 6, lines 14-21.

Page 4, lines 10-17 of the specification discloses that it is well known that microorganisms including bacteria have the ability to bioaccumulate metals, and that metal-

containing bacteria can be prepared. *See* Page 5, line 3 to Page 6, line 5. Applicants assert that using the claims and the supporting disclosure in the specification, one skilled in the art can, without undue experimentation, ascertain which bacteria can accumulate metals and minerals and which cannot accumulate metals and minerals in accordance with the invention.

As earlier discussed, the specification provides one prophetic example which clearly sets forth the concept of the present invention as claimed. Importantly, the Examiner should be aware that compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether a working example is disclosed. The Examiner's requirement that the specification disclose evidence that the bacteria claimed in the present invention can "grow to appreciable numbers" would necessitate the disclosure of a working example which is beyond the prescription for enablement under 35 U.S.C. §112, first paragraph.

An applicant need not have actually reduced the invention to practice prior to filing. For example, in Gould v. Quigg, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "[t]he mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." Id.

The specification need not contain an example of the invention which is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *See In re Borkowski*, 164 USPQ 642 (CCPA 1970). When considering the factors relating to a determination of non-enablement, if all the other factors point toward enablement, then the absence of working examples will not by itself render the

invention non-enabled. In other words, lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement. *See* MPEP §2164.02. To make a valid rejection, one must evaluate all the facts in evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims. Id.

In the present application, the Applicants have shown that *Cyanobacteria*, which are known symbionts, are of the same genus as known-bioaccumulators. The specification further discloses the high degree of symbiosis known between the disclosed bacteria and sponges and clearly states the concept of the invention in such a way that one of ordinary skill in the art could on the basis of the teaching reduce the invention to practice. Even if the skilled artisan were required to engage in any "trial and error" experimentation as the Examiner contends, the effort would not be "undue" but under the guidance of the specification would be a routine matter to obtain the present invention as disclosed and claimed.

Reconsideration and withdrawal of the reaction of Claims 23, 26, 28, 29, and 31 under 35 U.S.C. §112, first paragraph, are respectfully requested.


CONCLUSION

In light of the above, Applicants believe that this application is now in condition for allowance and therefore requests favorable consideration.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

PIPER RUDNICK LLP



Steven B. Kelber
Registration No. 30,073
Attorney of Record

1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2412
Telephone No. (202) 861-3900
Facsimile No. (202) 223-2085

Perry E. Van Over
Registration No. 42,197